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WHAT IS CLAIMED IS:

- A method for substantially reducing the range in daily dosages required to control pain in human patients, comprising administering an oral controlled 5 release dosage formulation comprising from about 10 to about 40 mg oxycodone or a salt thereof which provides a mean maximum plasma concentration of oxycodone from about 6 to about 60 ng/ml from a mean of about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration from about 3 to about 30 ng/ml from a mean of about 10 to about .14 hours after repeated administration every 12 hours through steady-state conditions.
- A method for substantially reducing the range in daily dosages required to control pain in substantially all human patients, comprising administering an oral solid controlled release dosage formulation comprising from about 10 mg to about 160 mg oxycodone or a salt thereof which provides a mean maximum plasma concentra-20 tion of oxycodone up to about 240 ng/ml from a mean of up to about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration up to about 120 ng/ml from a mean of about 10 to about 14 hours after repeated administration every 12 hours through steady-state conditions.
 - A controlled release exycodone formulation for oral administration to human partients, comprising from about 10 to about 40 mg oxycodone or a salt thereof, said formulation providing a mean maximum plasma concentration of oxycodone from about 6 to about 60 ng/ml from a mean of about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration from about 3 to about 30 ng/ml from a mean of about 10 to about 14 hours after

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repeated administration every 12 hours through steadystate conditions.

- A controlled release oxycodone formulation for 5 oral administration to human patients, comprising from about 10 mg to about 160 mg oxycodone or a salt thereof, said formulation providing a mean maximum plasma concentration of oxydodone from about 6 to about 240 ng/ml from a mean of about 2 to about 4.5 hours after administra-10 tion, and a mean minimum plasma concentration from about 3 to about 120 ng/ml from a mean of about 10 to about 14 hours after repeated administration every 12 hours through steady-state conditions.
- A solid controlled release oral dosage form, 5. 15 comprising
 - (a) oxygodone or a salt thereof in an amount from about 10 to about 160 mg;
 - (b) an effective amount of a controlled release matrix selected from the group consisting of hydrophilic polymers hydrophobic polymers, digestible substituted or unsubstituted hydrocarbons having from about 8 to about 50 carbon atoms, polyalkylene glycols, and mixtures of any of the foregoing; and
- (c) a suitable amount of a suitable pharmaceutical diluent wherein said composition provides a mean maximum plasma concentration of oxycodone from about 6 to about 240 ng/ml from a mean of about 2 to about 4.5 hours after administration, and a mean minimum 30 plasma concentration from about 3 to about 120 ng/ml from a mean of about 10 to about 14 hours after repeated administration every 12 hours through steady-state conditions.

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- The controlled release composition of claim 5, wherein said controlled release matrix comprises an acrylic resid.
- A solid controlled release oral dosage form, 7. 5 comprising
 - (a) \ an analgesically effective amount of spheroids comprising oxycodone or a salt thereof and either a spheronising agent or an acrylic polymer or copolymer, such that the total dosage of oxycodone in said dosage form is from about 10 to about 160 mg;
 - (b) a film coating which controls the release of the oxycodone oxycodone salt at a controlled rate in an aqueous medium, wherein said composition provides an in vitro dissolution rate of the dosage form;

said composition providing a mean maximum plasma concentration of oxycodone from about 6 to about 240 ng/ml from a mean of about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration from about 3 to about 30 ng/ml from a mean of about 10 to about 14 hours after repeated administration every 12 hours through steady state conditions.

- The controlled release composition of claim 7, wherein said film coating comprises a water insoluble material selected from the group consisting of shellac or zein, a water insoluble cellulose, or a polymethacrylate.
- A controlled release tablet for oral adminis-30 tration comprising from about 10 to about 160 mg oxycodone or an oxycodone salt dispersed in a controlled release matrix, said tablet providing an in-vitro dissolution of the dosage form, when measured by the USP Paddle Method at 100 rpm at 900 ml aqueous buffer (pH 35 between 1.6 and 7.2) at 37° C, between 12.5% and 42.5%

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(by wt) oxycomone released after 1 hour, between 25% and 55% (by wt) oxycodone released after 2 hours, between 45% and 75% (by wt) oxycodone released after 4 hours and between 55% and 85% (by wt) oxycodone released after 6 5 hours, the in vatro release rate being substantially independent of pH and chosen such that a mean maximum plasma concentration of oxycodone from about 6 to about 240 ng/ml is obtained in vivo from a mean of about 2 to about 4.5 hours after administration of the dosage form, and a mean minimum plasma condentration from about 3 to about 30 ng/ml from a mean of about 10 to about 14 hours after repeated administration every 12 hours through steady-state conditions.

- 10. A dosage form according to claim 9, wherein the 15 in vitro dissolution rate is between 17.5% and 38% (by wt) oxycodone released after 1 hour, between 30% and 50% (by wt) oxycodone released after 2 hours, between 50% and 70% (by wt) oxycodone released after 4 hours and between 20 60% and 80% (by wt) pxycodone released after 6 hours.
 - 11. A dosage form according to claim 9, wherein the in vitro dissolution rate is between 17.5% and 32.5% (by wt) oxycodone released after 1 hour, between 35% and 45% (by wt) oxycodone released after 2 hours, between 55% and 65% (by wt) oxycodone released after 4 hours and between 65% and 75% (by wt) oxycodone released after 6 hours.

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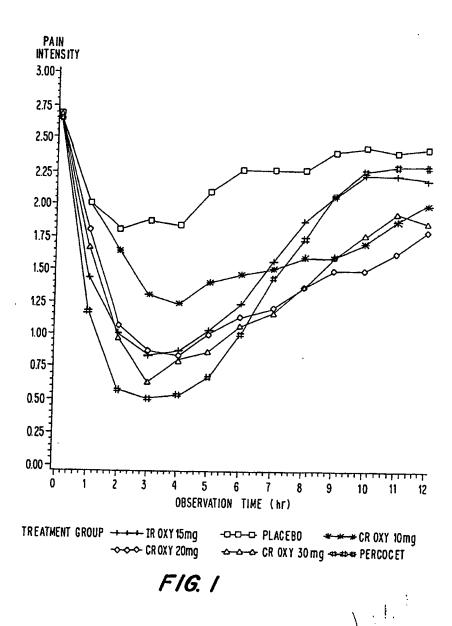
ABSTRACT OF THE DISCLOSURE

A method for substantially reducing the range in daily dosages required to control pain in approximately 90% of patients is disclosed whereby an oral solid controlled release dosage formulation having from about 10 to about 40 mg of oxycodone or a salt thereof is administered to a patient. The formulation provides a mean maximum plasma concentration of oxycodone from about 6 to about 60 ng/ml from a mean of about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration from about 3 to about 30 ng/ml from about 10 to about 14 hours after repeated "q12h" (i.e., every 12 hour) administration through steady-state conditions. Another embodiment is directed to a method for substan-15 tially reducing the range in daily dosages required to control pain in substantially all patients by administering an oral solid controlled release dosage formulation comprising up to about 160 mg of oxycodone or a salt thereof, such that a mean maximum plasma concen-20 tration of oxycodone up to about 240 ng/ml from a mean of up to about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration up to about 120 ng/ml from about 10 to about 14 hours after repeated "ql2h" (i.e., every 12 hour) administration through steady-state conditions are achieved. Controlled release oxycodone formulations for achieving the above are also disclosed.

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	CONTROLLED RELEASE OX	YCODONE COMPOSIT	IONS		
	the specification of which (check one)	☑ is attached hereto.	and was amend	ad on	(il applicable)
~	☐ was filed on	undersland the contents of the	above identified specified to the part of	cation, including the cleantability of this appropriately for pate	aims, as amended by any plication as defined in Title ant or inventor's certificate
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	I hereby claim the benefit under Tille 35, I matter of each of the claims of this applica of Title 35, United States Code, §112, I ac §1.56 which occurred between the filing	ition is not disclosed in the prior t	Jnited States application:	fined in Title 37, Code o	f Federal Regulations.
	07/800,549	November 27 (Filing Date)	1991	Pending	
•	(Application Serial No.)	(Filing Date)	(Status) (patented, pen	ding, abandoned)
	PCT/US92/10146 (Application Serial No.)	November 25, (Filing Date)	1992	<u>Pend i ng</u> Status) (patented, pen	ding, abandoned)
	And I hereby appoint Harold D. Steinbe Registration No. 32,728 my attorneys, withe Patent and Trademark Office conne York, N.Y. 10036; Telephone: 212-768-3 I hereby declare that all statements ma believed to be true; and further that the punishable by fine or imprisonment, or bo jeopardize the validity of the application	th full power of substitution and ricted therewith; correspondence 800; Fax: 212-382-2124. de herein of my own knowledg se statements were made with th, under Section 1001 of Tille 16 or any patent issued thereon.	e address: STEINBERG e are true and that all si the knowledge that will of the United States Cod	& RASKIN, 1140 Aver atements made on inf	ormation and belief are
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	Inventor, if any John Joseph	h mmrare	_ Fourth Inventor's signatu		Kou to
3	Third inventor's signature (1943)		_ Date	MATI	4, 1883
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	Post Office Address 33 East G	rand Street.B-2B		-	100us Road
	Mount Vernon, NY 1	0552	Weston, CT	06883	
	Full name of joint		Full name of joint		
	inventor, if any		Inventor, if any	}	
	Fifth Inventor's signature		_ Date		
	Date				

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'042 - 47

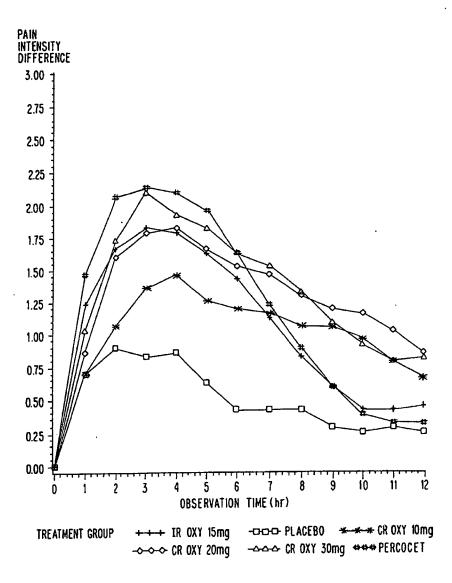
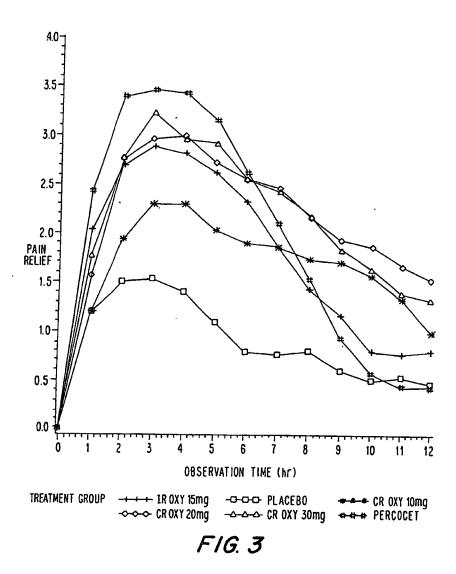
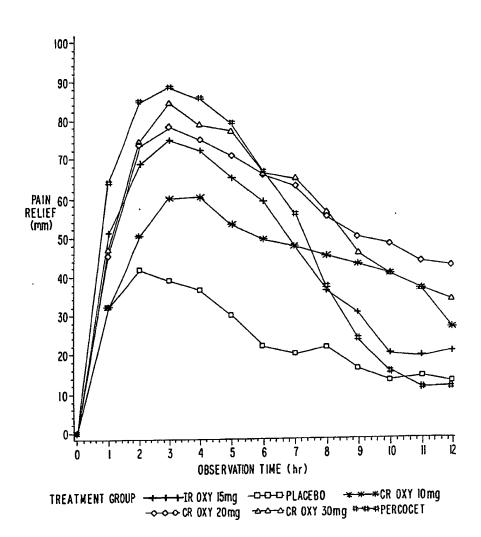


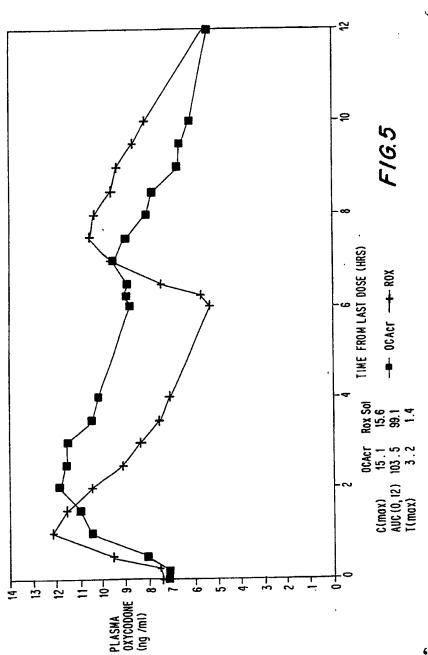
FIG.2



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F/G. 4



'042 - 51

FORM 54 (MODIFIED) DIVISIONAL-CONTINUATION PROGRAM APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE Cassaway

Docket No. 20093311.DIV

Anticipated Classification of this 8-19-95
application:

514 Class Subclass 282

Prior application: 08/081,302

Examiner <u>E. Webman</u> Art Unit <u>1502</u>

The Commissioner of Patents and Trademarks Washington, D.C. 20231

June 6, 1995

sir:

This is a request for filing a divisional application under 35 C.F.R. §1.60 of pending prior application Serial No. 08/081,302, filed on June 18, 1993.

For: CONTROLLED RELEASE OXYCODONE COMPOSITIONS

- Enclosed is a copy of the prior application including the oath or declaration as originally filed and an affidavit or declaration verifying it as a true copy. (See 8 and 8a for drawing requirements.)
- [] Prepare a copy of the prior application.

"Express Mail" mailing label no. TB 639 428 042 US
Date of deposit: June 6, 1995
I hereby certify that this correspondence and/or fee is being
I hereby certify that but that States Postal Service "Express Mail
Post Office to Addresses" service under 37 CFR 1.10 on the
date indicated above in envelope addressed to "Commissioner
of Patents and Trademarks, Washington, DC 20231"
STEINBERG, RASKIN & DAVIDSON, P.C.

Olive Cherin

[X] The filing fee is calculated below:

	FILED IN THE AIMS CANCELLE			
For	Number filed	Number extra	Rate	Basic fee \$730.00
Total claims Independent claims Total filing fee	2 - 20 = 2 - 3 =	0	× 22 × 76	0.00 <u>0.00</u> \$730.00

- 4. [X] The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Account No. 19-4210. A duplicate copy of this sheet is enclosed.
- 5. [X] A check in the amount of \$730.00 is enclosed.
- 6. [X] Cancel in this application original claims 3-11 of the prior application (without prejudice) before calculating the filing fee. (At least one original independent claim must be retained for filing purposes.)
- Amend the specification by inserting before the first line the sentence: This is a divisional of application Serial No. 08/081,302, filed June 18, 1993, which is a continuation-in-part of U.S. Application Serial No. 07/800,549, filed November 27, 1991, now U.S. Patent No. 5,266,331.
 - Transfer the drawings from the prior application to this application and abandon said prior application as of the 8. [] filing date accorded to this application. A duplicate copy of this sheet is enclosed for filing in the prior application file. (May only be used if signed by person authorized by Rule 138 and before payment of base issue fee.)
 - 8a. [X] New formal drawings are enclosed.
 - [] Priority of application in Serial No. filed on under 35 U.S.C. §119. 8b.
 - [] The certified copy has been filed in prior applica-, filed tion, Serial No.

- The prior application is assigned of record to 9. [X] Euroceltique, S.A.
- The power of attorney in this prior application is to Harold D. Steinberg, Reg. No. 17,255, Martin G. Raskin, Reg. No. 25,642, and Clifford M. Davidson, Reg. No. 23,730, 1140 Avenue of the American Very Very No. 10. [X] 32,728, 1140 Avenue of the Americas, New York, N.Y. 10036.
 - a. [X] The power appears in the original papers in the prior application.
 - [] Since the power does not appear in the original papers, a copy of the power in the prior application is enclosed.
 - c. [X] Address all future communications to Steinberg,
 Raskin & Davidson, P.C. 1140 Avenue of the
 Americas, New York, N.Y. 10036, Tel. (212) 768-3800.
- 11. [] A preliminary amendment is enclosed. (Claims added by this amendment have been properly numbered consecutively begin-ning with the number next following the highest numbered original claim in the prior application).
- 12. [X] I hereby verify that the attached papers are a true copy of prior application Serial No. 08/081,302, as originally filed on June 18, 1993.

The undersigned declare further that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that those statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

eritiord M. Davidson Attorney of Record Reg. No. 32,728

Steinberg, Raskin & Davidson, P.C. 1140 Avenue of the Americas New York, New York 10036 (212) 786-3800

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UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office. Address: COMMISSIONER OF PATENTS AND TRADEMARKS

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			DATE	MAILED:	
This is a communication from the examiner in characteristics and TRADEMA					
This application has been examined	Responsive to communic	cation filed on			This action is made fina
A shortened statutory period for response to this a Failure to respond within the period for response		month(s), loned. 35 (days from J.S.C. 133	the date of this letter.
Part 1 THE FOLLOWING ATTACHMENT(S) AR	RE PART OF THIS ACTIO	N:			
Notice of References Cited by Examin Notice of Art Cited by Applicant, PTO- Information on How to Effect Drawing	1449.				nt Drawing Review, PTO-94 optication, PTO-152.
Part II SUMMARY OF ACTION					
1. Claims	1,2		<u> </u>	a	re pending in the application
Of the above, claims	· · · · · · · · · · · · · · · · · · ·			are wi	thdrawn from consideration.
2. Claims				h	ave.been cancelled.
3. Claims				e	
4. Claims	2			a	re rejected.
5. Claims				8	re objected to.
6. Claims			are subject	to restriction o	r election requirement.
7. This application has been filed with inform	nal drawings under 37 C.F.	R. 1.85 which ar	e acceptabl	e for examinat	ion purposes.
8. Formal drawings are required in response					
The corrected or substitute drawings have are □ acceptable; □ not acceptable (see	been received on	Draftsman's Pate	ent Drawing	Under 37 C.F.I Review, PTO	R. 1.84 these drawings 948).
The proposed additional or substitute she examiner; disapproved by the examin	et(s) of drawings, filed on				
11. The proposed drawing correction, filed		sbeen 🗆 appro	oved; 🗖 di	sapproved (se	e explanation).
12. Acknowledgement is made of the claim for been filed in parent application, serial n	r priority under 35 U.S.C.	119. The certifie ; filed on	d copy has	□ been rece	ved not been received
13. Since this application apppears to be in conaccordance with the practice under Ex par	ndition for allowance exce te Quayle, 1935 C.D. 11;	pt for formal mat 453 O.G. 213.	ters, prosec	cution as to the	ments is closed in
14. Ciber					

EXAMINER'S ACTION

Serial Number: 08/467,584

-2-

Art Unit: 1502

Claims 1, 2 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to that which is disclosed as critical. See M.P.E.P. §§ 706.03(n) and 706.03(z).

On page 11, lines 24-28 a ratio of hydroxyalkyl cellulose to aliphatic alcohol or polyalkylene glycol of 1:2-1:4 is disclosed as determinative of the release rate of oxycodone. No other ratio is specified. However, claims 1, 2 specify no ratio at all. Thus, the specification is insufficient to support the breadth of the claims.

Claims 1, 2 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

No where in claims 1, 2 is the vehicle disclosed which delivers the active agent at the claimed rate. No ingredients are specified.

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Serial Number: 08/467,584

Art Unit: 1502

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention.

On page 10, line 31 - page 11, line 13 suggested ingredients are recited.

However, it is unclear precisely which are present in the vehicle, since all are optional.

Claims 1, 2 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

No claims are allowed.

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Serial Number: 08/467,584

Art Unit: 1502

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman, whose telephone number is (703) 308-4432. The examiner can normally be reached on Monday-Friday from 9:30 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703) 308-2927. The fax phone number for this Group is (703) 305-5408.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-2351.

Edward J. Webman:cb Primary Examiner

Wednesday, November 1, 1995

EDWARD J. WEBMAN PRIMARY EXAMINER GROUP 1500

Form PTO 948 (Rev. 10-94)

U.S. DEPARTMENT OF COMMERCE - Patent and Trademark Office

NOTICE OF DRAFTSPERSON'S PATENT DRAWING REVIEW

PTO Draftpersons review all originally filed drawings regardless of which they are designated as formal or informal. Additionally, patent Examiners will review the drawings for compliance with the regulations. Direct telephone inquiries concerning this review to the Drawing Review Branch, 703-305-8404.

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Indicated below. The Examiner will require subfullsion of new corrected I DTC 12 12 That thing not indicated for sectional portions of an object.	ı
drawings when necessary. Corrected drawings must be submitted Fig(s)	
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UNITED STATES PATENT AND TRADEMARK OFFICE

Re:

Application of:

Benjamin OSHLACK et al.

Serial No .:

08/467,584

Filed: For:

June 6, 1995

CONTROLLED RELEASE OXYCODONE

Filed 09/21/2007

COMPOSITIONS

INFORMATION DISCLOSURE STATEMENT

Hon. Commissioner of Patents and Trademarks Washington, D.C. 20231

October 13, 1995

Youngh Cranfold By No 34, 453-

Sir:

Applicants hereby submit PTO Form 1449 which lists references cited during the prosecution of the priority applications U.S. Serial No. 07/800,549 filed November 27, 1991 and 08/081,302 filed June 18, 1993. Copies of the references cited were submitted during the prosecution of the parent applications.

This Information Disclosure Statement is being filed prior to the issuance of the first Office Action, therefore, it is respectfully submitted that no fee is due.

It is respectfully requested that these references be considered and made of record.

Respectfully submitted,

STEINBERG, RASKIN & DAVIDSON, P.C.

Steinberg, Raskin & Davidson, P.C. 1140 Avenue of the Americas New York, New York 10036 (212) 768-3800

I hereby certify that this correspondence and/or fee is being deposited with the United States Postal Service as first class mail in an envelope addressed to: "Commissioner of Patents and Trademarks, "Commissioner of Patents and Trade Washington, D.C. 20231" on Octobe STEINBERG, RASKIN& DAVIDS

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UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SERIAL NUMBER FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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STEINBERG RASKIN & DAVIDSON 1140 AVENUE OF THE ASLATIAN NEW YORK MY 19036	M1/1226	APT UNIT PAPER NUMBER 5
EXAMINER IN	TERVIEW SUMMARY REC	ORD 12/26/95
All participants (applicant, applicant's representative, PTO personn	nel):	22.
(1) Mr. C. M. Davidson		
(2) E, Webman	(4)	
Date of Interview 12/18/95		•
Type: X Telephonic Personal (copy is given to applied		na)
Exhibit shown or demonstration conducted:	f yes, brief description:	
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Agreement 🙎 was reached with respect to some or all of the clai	ims in question. 🔲 was not rea	iched.
Identification of prior art discusted A N/A		
Description of the general nature of what was agreed to if an agree	ment was reached, or any other c	omments: to bring the case into
condition for allowance, it ws agreed		
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(A fuller description, if necessary, and a copy of the amendment attached. Also, where no copy of the amendments which would return the state of the	he contrary, A FORMAL WRITT	EN RESPONSE TO THE LAST OFFICE ACTION IS
☐ It is not necessary for applicant to provide a separate recor		
Since the examiner's interview summary above (including requirements that may be present in the last Office action response requirements of the last Office action.	any attachments) reflects a com n, and since the claims are now all	pless response to each of the phiactions, rejections and
	Exami	ner's Signature





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Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

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STEINBERG R	ASKIN & DAV	IDSON	ART UNIT	PAPER NUMBER
1140 AVENUE NEW YORK NY	OF THE AMER 10036	(10pg	1500	6 /B
			DATE MAILED.	12/26/95

NOTICE OF ALLOWABILITY

ART I.	KARER	PHONE	CALL	op_	12/18/95
this communication is responsive to All the claims being allowable, PROSECUTION ON herewith (or previously mailed), a Notice Of Allowan	THE MERITS IS (OR	REMAINS) CLO	SED in this	s applica	ition. If not included
course. ; 2					
The allowed claims are	oro accentable			_	
4. The drawings filed on	are acceptable.	The certified Co	nov bas [_]	been re	ceived. [_] not been
seceived. [] been filed in parent application Serial No	under 35 U.S.C. 119.	filed on			
6. Note the attached Examiner's Amendment.	. ==== 440				
7. Note the attached Examiner Interview Summary Reco	ord, PTOC-413.				
8. Note the attached Examiner's Statement of Reasons	for Allowance.				
9. Note the attached NOTICE OF REFERENCES CITED.	PTO-892.				
Note the attached INFORMATION DISCLOSURE CITA	ATION, PTO-1449.				
ART II. SHORTENED STATUTORY PERIOD FOR RESPONSE to ROM THE "DATE MAILED" indicated on this form. Fai xtensions of time may be obtained under the provisions of 3	37 CFR 1.136(a).	,			
. Note the attached EXAMINER'S AMENDMENT or N	OTICE OF INFORMAL	APPLICATION	PTO-152,	which di	scloses that the oath
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b. The proposed drawing correction filed on		has been app	roved by th	e exami	ner. CORRECTION IS
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REQUIRED. c. Approved drawing corrections are described by REQUIRED.	the examiner in the	attached EXAM	IINER'S AM	IEMONIE	NT. COMILECTION IS
d. Formal drawings are now REQUIRED.					
Any response to this letter should include in the upper ri AND ISSUE FEE DUE: ISSUE BATCH NUMBER, DATE OF T	ight hand corner, the HE NOTICE OF ALLOV	following inform	etion from	the NOT	ICE OF ALLOWANCE
Attachments:		laformal Applymatic	n PTO-152		
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Examiner Interview Summary Record, PTOL- 413		Bonded Draftsmen			
Reasons for Allowance	_ Other				
Notice of References Cited, PTO-892	2 01112				
Information Disclosure Citation, PTO-1449					

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Serial Number: 08/467584 Art Unit: 1502

The following is an Examiner's Statement of Reasons for Allowance: None of the references of record singly anticipate or in combination motivate one with ordinary skill in the art to formulate the particular method for reducing the dosage of oxycodone as set forth in the claims.

Any comments considered necessary by applicant must be submitted no later than the payment of the Issue Fee and, to avoid processing delays, should preferably accompany the Issue Fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Authorization for this Examiner's Amendment was given in a telephone interview with Mr. C. M. Davidson on 12/18/95.

An Examiner's Amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 C.F.R. § 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the Issue Fee.

In claim 1 line 1 and claim 2 line 1 delete 'substantially'.

Edward J. Webman December 24, 1995

EDWARD J. WEBMAN PRIMARY EXAMINER **GROUP 1500**



UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

Address: Box ISSUE FEE COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

15M1/1226

STEINBERG RASKIN & DAVIDSON 1140 AVENUE OF THE AMERICAS NEW YORK NY 10036

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

☐ Note attached communication from ☐ This notice is issued in view of appl		od		
SERIES CODE/SERIAL NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
90/462-584 06/	06/95 - 00	2 Webman,	<u>B</u> 1502 1	2/26/95
Applicant OSHLACK,	E OXYCODONE	BENJAMIN COMPOSITIONS	;	

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THE APPLICATION IDENTIFIES ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

- I. Review the SMALL ENTITY Status shown above. If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:
 - A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the patent and Trademark Office of the change in status, or
 - B. If the Status is the same, pay the FEE DUE shown above.
- If the SMALL ENTITY is shown as NO:
- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, pay of 1/2 the FEE DUE shown above.
- II. Part B of this notice should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B should be completed and returned. If you are charging the ISSUE FEE to your deposit account, Part C of this notice should also be completed and returned.
- III. All communications regarding this application must give series code (or filing date), serial number and batch number. Please direct all communication prior to issuance to Box ISSUE FEE unless advised to contrary.

IMPORTANT REMINDER: Patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.



UNITED STATES PATENT & TRADEMARK OFFICE

Re:

Application of:

Benjamin OSHLACK et al.

Serial No.:

08/467,584

Filed:

June 6, 1995

For:

CONTROLLED RELEASE OXYCODONE

COMPOSITIONS

SUBMISSION OF FORMAL DRAWINGS

Commissioner of Patents and Trademarks Washington, D.C. 20231

January 17, 1996

Sir:

Applicants submit herewith formal drawings in connection with the above-identified patent application.

If it is determined that any further fees are due at this time, the Commissioner is hereby authorized to charge any such fees to Deposit Account No. 19-4210. .

Respectfully submitted,

STEINBERG, RASKIN & DAVIDSON, P.C.

Clifford M. Davidson

Reg. No. 32,728

Steinberg, Raskin & Davidson, P.C. 1140 Avenue of the Americas New York, New York 10036 (212) 768-3800

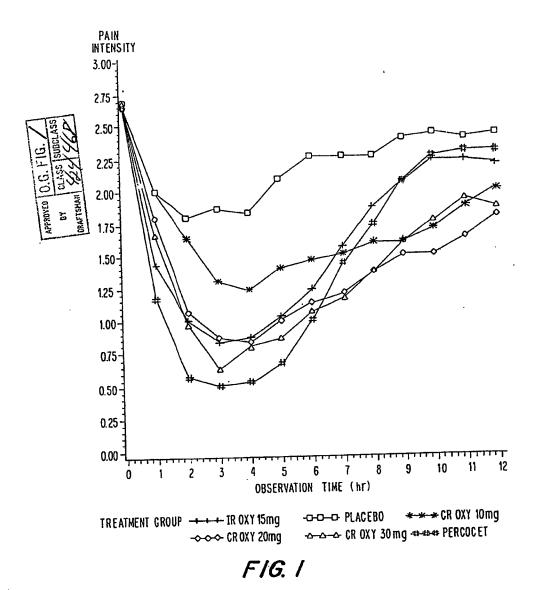
(212) 706-3000

I hereby certify that this correspondence and/or fee is being deposited with the United States Postal Service as "first class mail" in an envelope addressed to "Commissioner of Patents and Trademarks, Washington, D.C. 20231" on January 17, 1996.

STEINBERG, RASKIN & DAYIDSON, P.C.

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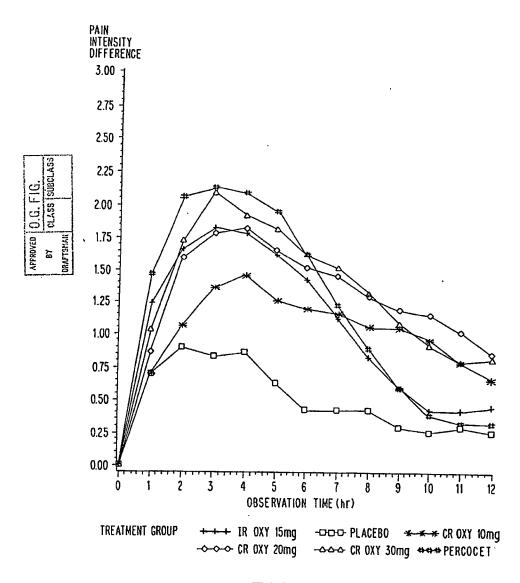
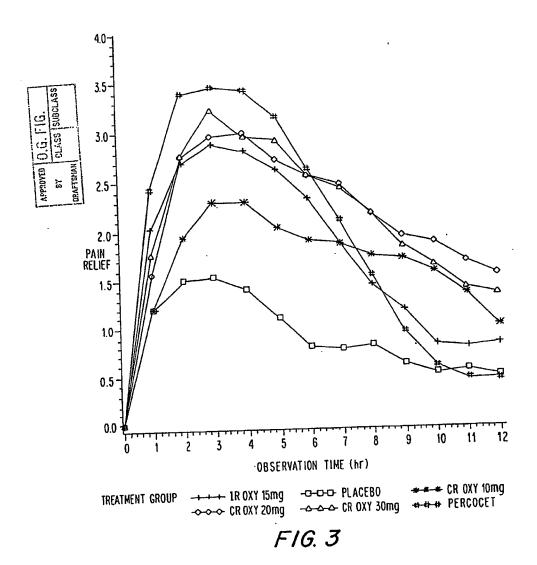
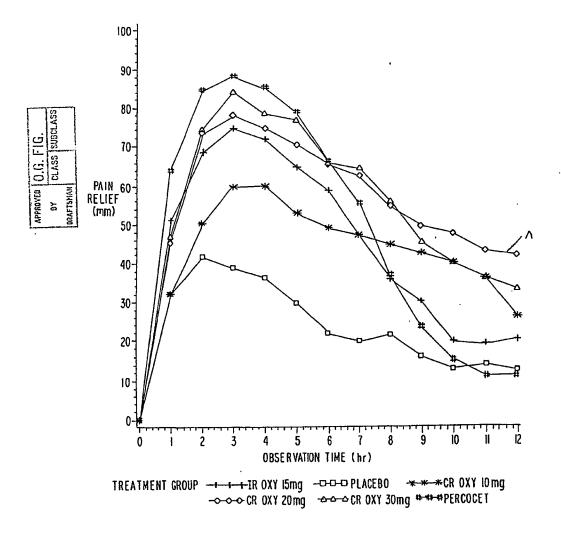


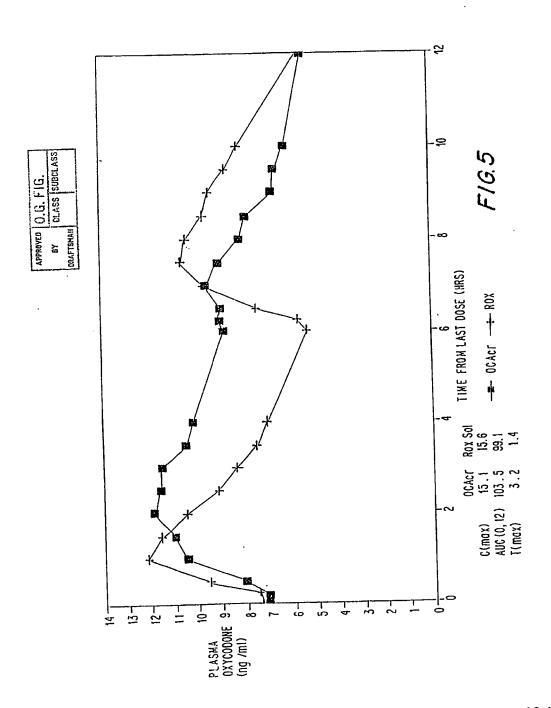
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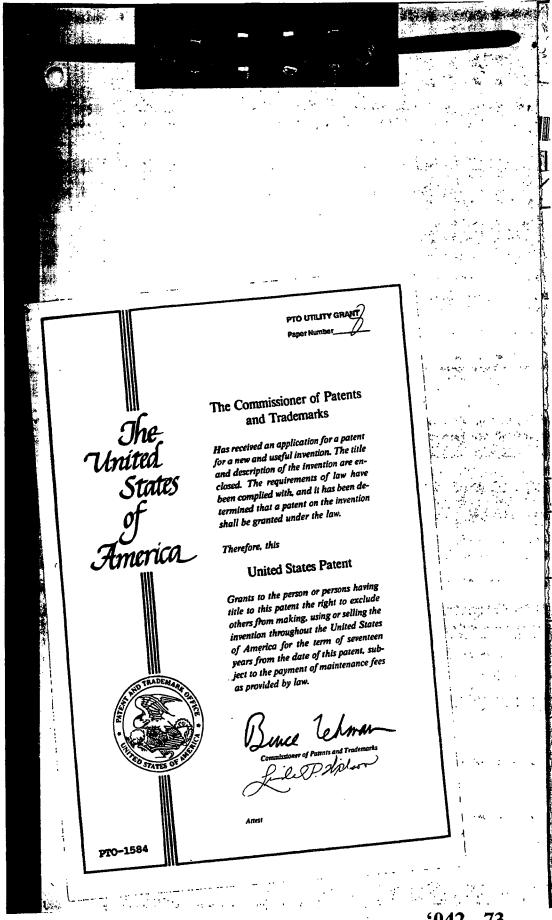


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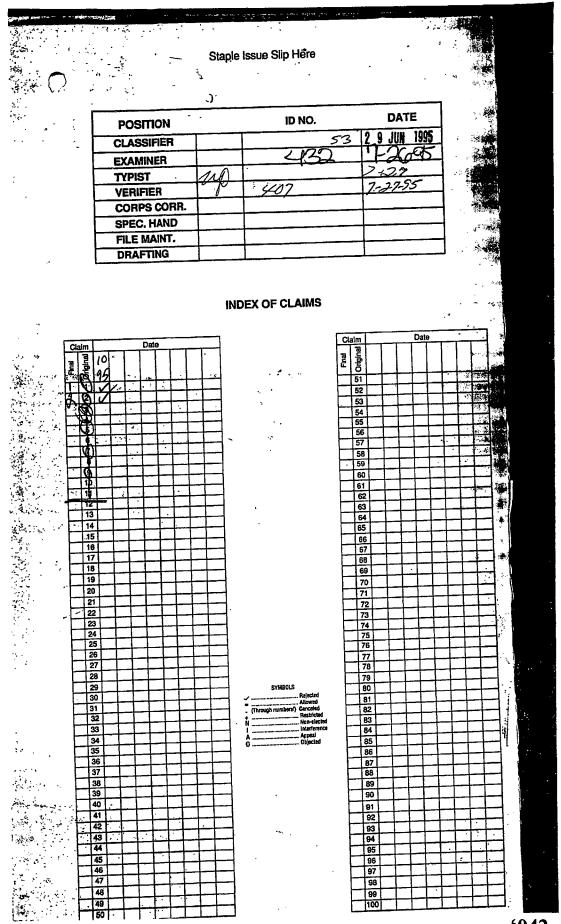


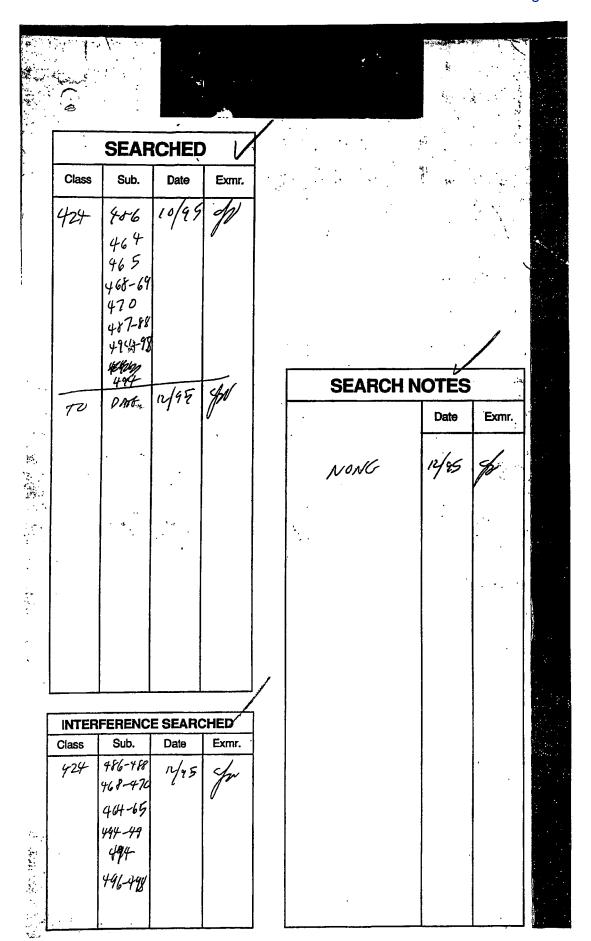
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Attn: Clifford M.	Davidson		no name v	vill be printed.	·
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